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10/517,468

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10/03/2008

EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

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DELIVERY MODE

10/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,468	Applicant(s) SUZUKI ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

The Examiner thanks the Applicants for their timely reply filed on 26 February 2008, in the matter of 10/517,468. A response to the remarks and amendments are herein presented under 37 CFR § 1.113.

The Examiner acknowledges the amendments made to claims 6, 7 and 10, as well as the instant specification regarding the replacement of the term “hard and flexible degree” with the term “bending stiffness”. The amendments made are acknowledged as corrections due to translational errors. The Examiner further acknowledges the amendment made to the Abstract as well as the correction of additional typographical errors throughout the instant specification.

The Examiner acknowledges that no new matter has been added.

Claims 1-12 still represent all claims currently presented for examination on the merits.

Response to Remarks

With regards to the amended Abstract, the Examiner acknowledges the definition provided. However, the last sentence of the Abstract still lacks clarity as a result of the amendment and thus the objection is **maintained**.

The Examiner acknowledges the amended title and the support thereto. Thus, the objection stands **withdrawn**.

The Examiner acknowledges the corrected spelling of the term “styrene” in the instant claims 6 and 7. Thus, the objection to the claims stands **withdrawn**.

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Applicants' amendment to claim 10 to "correct an inadvertent translational error" in further view of the submitted references renders the rejection under *35 USC §112, second paragraph* moot. Thus, said rejection is hereby **withdrawn**.

The rejection to claims 1, 6-9, 11 and 12 on the grounds of nonstatutory obviousness type double patenting as being unpatentable over claims 1 and 6-8 of Chono et al. (USPN 6,139,866) in view of claim 5 of Wick et al. (USPN 6,129,929) is **maintained**.

The rejection to claims 1-12 under 35 USC §103(a) as being unpatentable over Chono et al. (USPN 6,139,866) in view of Wick et al. (USPN 6,129,929) is **maintained**.

Information Disclosure Statement

No new Information Disclosure Statements have been submitted for consideration at this time.

The Examiner thanks Applicants for providing the references cited in the response dated 26 February 2008.

However, the listing of references in said response to the Office Action dated 26 October 2007 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP §609.04(a) states that the list of references must be submitted in a separate paper. Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

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MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Action dated 26 February 2008:

Specification

The abstract of the disclosure is objected to because the term “ μ mRa” is undefined.

Correction is required. See MPEP § 608.01(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-9, 11 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-8 of Chono et al. (U.S. Patent No. 6,139,866) in view of claim 5 of Wick et al. (U.S. Patent 6,129,929). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant

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claims 1, 6-9, 11 and 12 are broader and therefore more obvious to all that are recited in the patented claims 1 and 6-8 of Chono et al. (U.S. Patent 6,139,866), in further view of claim 5 of Wick et al. (U.S Patent 6,129,929).

Chono et al. teaches in claim 1, a tape formulation for percutaneous administration containing the narcotic analgesic fentanyl citrate in an adhesive layer containing two components of polyisobutylene and styrene-isoprene-styrene block copolymer as well as a tackifier. Claims 6-8 teach the instant claims 6-8, 11 and 12, in that the tape formulation contains fentanyl (e.g. a narcotic analgesic), and oils and tackifiers that may be formulated into the adhesive layer. However, Chono et al. does not teach the specified surface area of the instant claim 9.

Wick et al. teaches a transdermal patch applicator system (Abstract) comprised of a polyester-based backing layer and an adhesive layer comprising a drug (claim 8). The surface area of the patch, as cited in the instant claim 9, is taught to be 20 cm² or less (claim 5).

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to prepare a transdermal patch formulation comprising a silica-roughened backing layer and a drug-containing adhesive layer for percutaneous delivery of a drug from the adhesive layer with a reasonable expectation of success. Such would have been obvious in the absence of evidence to the contrary because Wick et al. teaches the use of various forms of silica (i.e. fumed, granulated sand), which are well known in the art as conveying surface roughness or abrasiveness the inclusion of which increase the friction between the backing and adhesive layers allowing for greater stability of the overall formulation.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (U.S. Patent 6,139,866) in view of Wick et al. (U.S. Patent 6,129,929).

Chono et al. teaches in claim 1, a tape formulation for percutaneous administration containing the narcotic analgesic fentanyl citrate in an adhesive layer containing two components of polyisobutylene and styrene-isoprene-styrene block copolymer as well as a tackifier. Polyethylene terephthalate (PET) is taught to comprise the backing layer (column 5, lines 44-48). However, Chono does not teach surface roughness, the establishment thereof, the thicknesses of the backing and adhesive layers, the area of the patch formulation or the hard and flexible degree of the substrate.

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Wick et al. teaches a transdermal patch applicator system (Abstract) comprised of a polyester-based backing layer (column 4, lines 47-57) ranging from 2-1,000 micrometers thick and an adhesive layer comprising a drug (claim 8). The formulation can be treated (e.g. “sandblasted” or sprayed) with fumed silica, reagent grade sand, or precipitated silica (column 4, lines 7-9) to convey rheological properties, although it is acknowledged that multiple functions or properties (i.e. surface roughness) can be attained through use of peripheral agents to the formulation (column 3, lines 63-65). The surface area of the patch is taught to be 20 cm² or less at claim 5. Transdermal patches are also well known in the art as possessing a general flexibility that allows for not only easier removal of the release liner, but also for easier conformation and application to the intended target (column 1, lines 19-23). As to the claimed ranges, the adjustment of particular working conditions (e.g. average roughness of a surface, thickness of a given layer, or degree of hardness and flexibility) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to prepare a transdermal patch formulation comprising a silica-roughened backing layer and a drug-containing adhesive layer for percutaneous delivery of a drug from the adhesive layer with a reasonable expectation of success. Such would have been obvious in the absence of evidence to the contrary because Wick et al. teaches the use of various forms of silica (i.e. fumed, granulated sand), which are well known in the art as conveying surface roughness or abrasiveness the inclusion of which increase the friction between the backing and adhesive layers allowing for greater stability of the overall formulation.

Response to Arguments

Applicants' amendments to the Abstract have been fully considered but are not persuasive.

With regards to the Abstract amendment, Applicants support the change by citing the instant specification at page 11, lines 2-4, which states that "Ra shows the central line mean roughness (cutoff value, 0.25 mm)." The Examiner maintains the objection, respectfully submitting that as a result of the amendment, the Abstract has been rendered further obscure, particularly due to the syntax of the last sentence. Clarification is requested.

Applicants' arguments with regards to both the nonstatutory obviousness type double patenting and 103(a) rejections over Chono in view of Wick have both been fully considered, but neither is persuasive.

With regards to the nonstatutory obviousness type double patenting (ODP) rejection, the Examiner notes that Applicants have acknowledged the rejection, both in written and oral contexts, but have filed no Terminal Disclaimer and have not amended the claims in such a manner which differentiates the subject matter from the previously rejected claims. Applicants' arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Essentially, in absence of a TD or amended claims, the burden shifts to Applicants to distinguish the instant claims from the conflicting claims of the art, notably from claims 1 and 6-8 of Chono in view of claim 5 of Wick

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et al. Since this distinction has not been provided in any of the aforementioned manners, the Examiner respectfully **maintains** the ODP rejection, in addition to the reasons already made of record.

With regards to the rejection of claims 1-12 under 103 over Chono in view of Wick, Applicants allege that the cited combination of references provide no teaching or suggestion regarding surface roughness of the backing layer in contact with the adhesive layer, thereby providing no teaching of improved anchoring properties over the instantly claimed patch. Applicants more specifically argue that Chono fails to provide any teaching or suggestion with respect to surface roughening and/or a polyester-based film with a surface roughness on the side of the polyester-based film in contact with the adhesive layer within the instantly claimed range. Applicants also argue that Wick does not teach or suggest the use of silica to convey surface roughness to increase friction between the layers or roughening the surface of the backing layer or adhesion of the drug-loaded adhesive layer to said roughened surface.

In response, the Examiner respectfully submits that Applicants are arguing limitations which are either properties of the claimed composition or product-by-process limitations. With regards to the limitation recited in claim 1, which states” “wherein the surface roughness of the polyester-based film surface on the side in contact with the adhesive layer is from 0.05 to 0.8 μmRa ”, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the patch composition which is instantly claimed. With regards to the recitation in claim 2, wherein the surface of the polyester-based film in contact with the adhesive layer is sandblasted, this limitation is deemed

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by the Examiner as a product-by-process limitation, which per MPEP §2113, holds no patentable weight. As such, claim 2 is broadly and reasonably interpreted by the Examiner as reciting the same examinable subject matter as claim 1.

In response to Applicants' argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of silica to convey surface roughness to increase friction between the layers or roughening the surface of the backing layer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Thus, as no evidence has been presented by Applicants on behalf of the aforementioned, the combination of references, as cited in the maintained 35 USC §103 rejection above, continue to read on and render obvious claims 1-12 of the instant application.

NEW REJECTIONS

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Independent claim 1 and dependent claims 2-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 is drawn to a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer laminated thereon. The claim further recites a surface roughness property, which is discussed above and which has the following range associated with it: “0.05 to 0.8 μmRa ”. While the Examiner acknowledges that the claimed range of “0.05 to 0.8 μm ”, a definition for the term “Ra” and the units “ μmRa ” are all mentioned in the instant specification, the instantly claimed “ μmRa ” units are not discussed by the instant specification in a clear and concise manner. For example, Applicants’ submitted remarks dated 26 February 2008, discuss the definition of the term “Ra” as stated on page 11, lines 2-4 of the instant specification. However, a part of that definition is quantitative such that the mean roughness has a cutoff value of 0.25mm, thereby, seemingly assigning measurable units to the term “Ra”. Thus as interpreted in the instant claims by the Examiner, the units “ μmRa ”, lack a clear and concise description. As such, the disclosure of the instant specification is not sufficient to support “0.05 to 0.8 μmRa ” as a range limitation for the instantly claimed surface roughness property limitation and requires further clarification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chono et al. (USPN 6,139,866).

The instant claims are directed to a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer laminated thereon (claims 1, 2 and 10). The limitations to claims 1 and 2 are discussed above. The “bending stiffness of a substrate” limitation recited in claim 10, is considered in the same light as the “surface roughness” limitation recited in claim 1, such that until some material difference(s) in the properties of the composition are presented, said limitation is considered to be directed towards the instantly claimed composition. Thicknesses for both the substrate and adhesive layers are recited (claims 3 and 4). Polyethylene terephthalate (PET) is recited as the material of the substrate (claim 5). The adhesive containing the block copolymer styrene-isoprene-styrene and polyisobutylene is recited (claims 6 and 7). The adhesive containing a tackifying agent, a plasticizer or both is recited (claim 8). Fentanyl or salts thereof as the narcotic analgesic agent of the composition are recited (claims 11 and 12).

The teachings to Chono et al. are discussed above. Chono further teaches a specific patch (e.g. tape) formulation which comprising an adhesive layer which itself comprises fentanyl, a tackifier, polyisobutylene and styrene-isoprene-styrene copolymer (claim 1 and Example 2).

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Example 2 further teaches applying a 100-micron thick adhesive layer to PET film layer having a thickness of 30 microns (col. 6, lines 25-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (U.S. Patent 6,139,866) in view of Wick et al. (U.S. Patent 6,129,929).

The instant claims are directed to a patch composition, as discussed above. Claim 9 further limits said composition by reciting an area range of 5-60 cm².

The teachings to Chono et al. are discussed above.

However, Chono provides no express teaching of the patch having a specified size or area, as claimed by Applicants. Since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. For example, as discussed above, Wick et al. teaches that patches may be optimally sized to provide easy of application, specifically pointing out that patches having a size of 20 cm² or smaller are preferred (Abstract, claim 5). Thus, it would have been customary for an artisan of ordinary skill, to adjust the area of the patch composition, in order to achieve the desired patch size. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

All claims have been rejected; no claims are allowed.

Conclusion

Due to the new grounds of rejection, this action is deemed **non-final**.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615